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Pilot phase I study using zidovudine in association with a 10-day course of anti-CD4 monoclonal antibody in seven AIDS patients.

Dhiver C, Olive D, Rousseau S, Tamalet C, Lopez M, Galindo JR, Mourens M, Hirn M, Gastaut JA, Mawas C.

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Experimental evidence has demonstrated that monoclonal antibody (MAb) 13B8.2, a workshop-qualified anti-CD4 MAb, (1) inhibits in vitro syncytium formation as well as in vitro HIV infection of CD4+ T cells; (2) delivers negative signals to T cells, thus preventing T-cell activation and viral replication; (3) contributes to CD4+ T-cell clearance by its Fc portion, and (4) induces an immune response by the patient, contributing potentially to an anti-idiotypic response of interest for the control of the immune parameters of the disease. On this basis a phase I study combining zidovudine treatment and a 10-day course of anti-CD4 MAb was performed in seven AIDS patients (Centers for Disease Control group IV). The treatment was well tolerated. MAb dosage and schedule were adjusted on the basis of circulating CD4+ cells and MAb pharmacokinetics; immunological and virological parameters were also monitored. One patient presented a transient increment in CD4+ T cells associated with augmented T-cell function, the suppression of p24 in the serum and a negative RT assay. A second patient had a steady increment of CD4+ T cells after completion of the treatment, with a transient decrease of serum p24 5 days after completion of the anti-CD4 protocol.

PMID: 2576628 [PubMed - indexed for MEDLINE]

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